

4/8

FORM PTO-1390 (Modified)  
(REV 11-2000)

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTORNEY'S DOCKET NUMBER

**TRANSMITTAL LETTER TO THE UNITED STATES  
DESIGNATED/ELECTED OFFICE (DO/EO/US)  
CONCERNING A FILING UNDER 35 U.S.C. 371**

**DEX-0184**

U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR  
**09/806,311**

INTERNATIONAL APPLICATION NO.  
**PCT/US99/22725**

INTERNATIONAL FILING DATE  
**30 September 1999**

PRIORITY DATE CLAIMED  
**2 October 1998**

TITLE OF INVENTION

**A Novel Method of Diagnosing, Monitoring, Staging, Imaging and Treating Gastrointestinal Cancers**

APPLICANT(S) FOR DO/EO/US

**MACINA, Roberto A.**

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☐ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☒ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☐ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (24) indicated below.
4. ☐ The US has been elected by the expiration of 19 months from the priority date (Article 31).
5. ☐ A copy of the International Application as filed (35 U.S.C. 371 (c) (2))
  - a. ☐ is attached hereto (required only if not communicated by the International Bureau).
  - b. ☐ has been communicated by the International Bureau.
  - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
  - a. ☐ is attached hereto.
  - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
  - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
  - b. ☐ have been communicated by the International Bureau.
  - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
  - d. ☐ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
10. ☐ An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).
11. ☐ A copy of the International Preliminary Examination Report (PCT/IPEA/409).
12. ☐ A copy of the International Search Report (PCT/ISA/210).

**Items 13 to 20 below concern document(s) or information included:**

13. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
14. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
15. ☐ A **FIRST** preliminary amendment.
16. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
17. ☐ A substitute specification.
18. ☐ A change of power of attorney and/or address letter.
19. ☐ A computer-readable form of the sequence listing in accordance with 37 CFR 1.821 through 1.825.
20. ☐ A second copy of the published international application.
21. ☐ A second copy of the English language translation of the published international application.
22. ☐ Certificate of Mailing by Express Mail.
23. ☐ Other items or information:

"Express Mail" Label No. **EV104364689US**  
Date of Deposit **April 30, 2002**

I hereby certify that this paper is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the U.S. Patent and Trademark Office, Box Sequence, P.O. Box 2327, Arlington, VA 22202

By Kathleen A. Tyndall  
Typed Name: Kathleen A. Tyndall, Reg. No. 38,350

**1) Notification of Defective Response; 2) Amendment under 1.825;  
3) Statement to Support Filing and Submission in Accordance with 37 CFR 1.821 through 1.825  
4) Substitute pages of the Sequence Listing; 5) Substitute copy of the computer readable form of Sequence Listing**

U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR 1.492(a)(1)-(5)) : <div style="text-align: center; font-weight: bold;">09/806,311</div>	INTERNATIONAL APPLICATION NO. <div style="text-align: center; font-weight: bold;">PCT/US99/22725</div>	ATTORNEY'S DOCKET NUMBER <div style="text-align: center; font-weight: bold;">DEX-0184</div>		
24. The following fees are submitted: <div style="border: 1px solid black; padding: 5px; margin-top: 5px;"> <b>BASIC NATIONAL FEE ( 37 CFR 1.492 (a) (1) - (5) ) :</b>  <input type="checkbox"/> Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO ..... <b>\$1040.00</b>  <input type="checkbox"/> International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO ..... <b>\$890.00</b>  <input type="checkbox"/> International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO ..... <b>\$740.00</b>  <input type="checkbox"/> International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4) ..... <b>\$710.00</b>  <input type="checkbox"/> International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4) ..... <b>\$100.00</b>  <div style="text-align: right; font-weight: bold;">ENTER APPROPRIATE BASIC FEE AMOUNT =</div> </div>		CALCULATIONS    PTO USE ONLY		
Surcharge of <b>\$130.00</b> for furnishing the oath or declaration later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492 (e)).		\$0.00		
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	
Total claims	- 20 =	0	x \$18.00	\$0.00
Independent claims	- 3 =	0	x \$80.00	\$0.00
Multiple Dependent Claims (check if applicable). <input type="checkbox"/>				\$0.00
TOTAL OF ABOVE CALCULATIONS =				\$0.00
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27). The fees indicated above are reduced by 1/2.				\$0.00
SUBTOTAL =				\$0.00
Processing fee of <b>\$130.00</b> for furnishing the English translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492 (f)).				\$0.00
TOTAL NATIONAL FEE =				\$0.00
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31) (check if applicable). <input type="checkbox"/>				\$0.00
TOTAL FEES ENCLOSED =				\$0.00
				Amount to be: refunded \$
				charged \$
a. <input type="checkbox"/> A check in the amount of _____ to cover the above fees is enclosed. b. <input type="checkbox"/> Please charge my Deposit Account No. _____ in the amount of _____ to cover the above fees. A duplicate copy of this sheet is enclosed. c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <b>50-1619</b> A duplicate copy of this sheet is enclosed. d. <input type="checkbox"/> Fees are to be charged to a credit card. <b>WARNING:</b> Information on this form may become public. <b>Credit card information should not be included on this form.</b> Provide credit card information and authorization on PTO-2038.				
<b>NOTE:</b> Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.				
SEND ALL CORRESPONDENCE TO:				
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <b>Jane Massey Licata, Reg. No. 32,257</b>  <b>Kathleen A. Tyrrell, Reg. No. 38,350</b>  <b>Licata &amp; Tyrrell P.C.</b>  <b>66 E. Main Street</b>  <b>Marlton, New Jersey 08053</b>   <b>Telephone: (856) 810-1515</b>  <b>Facsimile : (856) 810-1454</b> </div> <div style="width: 50%; text-align: right;">           SIGNATURE   <b>Kathleen A. Tyrrell</b>          NAME   <b>38,350</b>          REGISTRATION NUMBER   <b>April 30, 2002</b>          DATE       </div> </div>				



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents, Box PCT  
United States Patent and Trademark Office  
Washington, D.C. 20231  
www.uspto.gov

U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
09/806,311	Roberto A Macina	DEX-0184

INTERNATIONAL APPLICATION NO.
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PCT/US99/22725

I.A. FILING DATE	PRIORITY DATE
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09/30/1999

10/02/1998

Licata & Tyrrell  
66 East Main Street  
Marlton, NJ 08053

Docket System ✓  
Status Report ✓  
Docket Book ✓

CONFIRMATION NO. 8561

371 FORMALITIES LETTER



\*OC000000007754778\*

Date Mailed: 04/03/2002

05/03/02

Max 10/03/02

**NOTIFICATION OF DEFECTIVE RESPONSE**

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as an Elected Office (37 CFR 1.495):

- U.S. Basic National Fee
- Priority Document
- Assignee Statement
- Biochemical Sequence Diskette
- Biochemical Sequence Listing
- Copy of IPE Report
- Copy of references cited in ISR
- Copy of the International Application
- Copy of the International Search Report
- Information Disclosure Statements
- Oath or Declaration
- Preliminary Amendments

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

**Applicant is required to complete the response within a time limit of ONE MONTH from the date of this Notification or within the time remaining in the response set forth in the Notification of Missing Requirements, whichever is the longer. No extension of this time limit may be granted under 37 CFR 1.136, but the period for response set in the Notification of Missing Requirements may be extended under 37 CFR 1.136(a).**

The following items **MUST** be furnished within the period set forth below:

- The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 CFR 1.821-1.825 for the following reason(s):
  - A copy of the "Sequence Listing" in computer readable form has been submitted. The content of the

computer readable form, however, does not comply with the requirements of 37 CFR 1.822 and/or 1.832, as indicated on the attached marked-up copy of the "Raw Sequence Listing."

- The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A substitute computer readable form must be submitted as required by 37 CFR 1.825(d).
- APPLICANT MUST PROVIDE:
  - An initial or substitute computer readable form (CRF) of the "Sequence Listing."
  - An initial or substitute paper copy or compact disc of the "Sequence Listing," as well as an amendment directing its entry into the specification.

- For questions regarding compliance to 37 CFR 1.821-1.825 requirements, please contact:

- For Rules Interpretation, call (703) 308-4216
- To Purchase Patent Software, call (703) 306-2600
- For Patent Software Program Help, call (703) 306-4119 or e-mail at [patin21help@uspto.gov](mailto:patin21help@uspto.gov) or [patin3help@uspto.gov](mailto:patin3help@uspto.gov)

- A copy of the "Sequence Listing" in computer readable form has been submitted. The content of the computer readable form, however, does not comply with the requirements of 37 CFR 1.822 and/or 1.832, as indicated on the attached marked-up copy of the "Raw Sequence Listing."
- The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A substitute computer readable form must be submitted as required by 37 CFR 1.825(d).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

*A copy of this notice **MUST** be returned with the response.*

VONDA M WALLACE

Telephone: (703) 305-3736

#### PART 1 - ATTORNEY/APPLICANT COPY

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
09/806,311	PCT/US99/22725	DEX-0184

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No.: DEX-0184

Inventors: Roberto A. Macina

Serial No.: 09/806,311

Filing Date: Not yet assigned

Examiner: Not yet assigned

Group Art Unit: Not yet assigned

Title: A Novel Method of Diagnosing,  
Monitoring, Staging, Imaging and  
Treating Gastrointestinal Cancers

"Express Mail" Label No. EV1043646895US  
Date of Deposit - April 30, 2002

I hereby certify that this paper is being deposited with  
the United States Postal Service "Express Mail Post Office  
to Addressee" service under 37 CFR 1.10 on the date  
indicated above and is addressed to the U.S. Patent and  
Trademark Office, Box Sequence, P.O. Box 2327 Arlington, VA 22202

By

*Kathleen A. Tyrell*  
Typed Name: Kathleen A. Tyrell

U.S. Patent and Trademark Office  
Box Sequence, P.O. Box 2327  
Arlington, VA 22202

Sir:

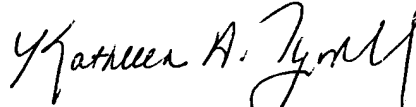
STATEMENT TO SUPPORT FILING AND SUBMISSION IN ACCORDANCE  
WITH 37 CFR §§ 1.821 THROUGH 1.825

- ( ) I hereby state, in accordance with the requirements of 37  
C.F.R. §1.821(f), that the contents of the paper and  
computer readable copies of the Sequence Listing, submitted  
in accordance with 37 CFR §1.821(c) and (e), respectively  
are the same.
- ( ) I hereby state that the submission filed in accordance with  
37 CFR §1.821(g) does not include new matter.

Rec'd PCT/PTO 30 APR 2002

- ( ) I hereby state that the submission filed in accordance with **37 CFR §1.821(h)** does not include new matter or go beyond the disclosure in the international application as filed.
- (XX) I hereby state that the amendments, made in accordance with **37 CFR §1.825(a)**, included in the substitute sheet(s) of the Sequence Listing were made to conform with the current Sequence Listing rules. I hereby state that the substitute sheet(s) of the Sequence Listing does not include new matter.
- (XX) I hereby state that the substitute copy of the computer readable form, submitted in accordance with **37 CFR §1.825(b)**, is the same as the amended Sequence Listing.
- ( ) I hereby state that the substitute copy of the computer readable form, submitted in accordance with **37 CFR §1.825(d)**, contains identical data to that originally filed.

Respectfully submitted,



Kathleen A. Tyrrell  
Registration No. 38,350

Date: April 30, 2002

Licata & Tyrrell P.C.  
66 E. Main Street  
Marlton, New Jersey 08053

(856) 810-1515